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August 26, 2013

Contains Confidential Information
Filed Under Seal

VIA ECF
Honorable Joel A. Pisano, U.S.D.J.
United States District Court
District of New Jersey
Clarkson S. Fisher Federal Bldg. & U.S. Courthouse
402 East State Street
Room 6052
Trenton, NJ 08608

Re: ***AstraZeneca v. Hanmi***
Civil Action No.: 11-760(JAP)(TJB)

Dear Judge Pisano:

This firm, along with Sughrue Mion, PLLC, represents the Hanmi Defendants ("Hanmi") in the above-captioned Hatch-Waxman patent infringement action brought by Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively "AstraZeneca").

We write concerning a schedule for responding to AstraZeneca's recent "Motion for Injunction Pending Appeal," including the need for expedited discovery (D.I. 345). Unfortunately, despite the parties' communications by email and by telephone, we are unable to agree on the scope of discovery and an appropriate schedule.

Hanmi respectfully requests an opportunity to conduct focused, expedited discovery in order to be able to fairly and fully respond to AstraZeneca's allegations of irreparable harm and related arguments, according to the following schedule:

- August 30, 2013 -- AstraZeneca completes production of all documents responsive to Hanmi's requests served Friday, August 23, 2013 (*see* Ex. A, Scherling to Renk, with discovery requests)
- September 20, 2013 -- Hanmi concludes depositions of AstraZeneca fact and 30(b)(6) witnesses (*see* Ex. A)
- September 30, 2013 -- Hanmi Opposition and supporting evidence due
- October 7, 2013 -- AstraZeneca Reply due

Narrowly-focused discovery on matters bearing on injunctive relief not addressed prior to the parties' settlement is necessary for Hanmi to respond to AstraZeneca's motion. Such focused discovery is routinely permitted on motions for injunctive relief. *See, e.g., Sawhorse Enterprises, Inc. v. Church & Dwight Co., Inc.*, 2013 U.S. Dist. LEXIS 48155, *11-12 (D.N.J.

April 3, 2013) (discussing propriety of narrowly-tailored discovery on preliminary injunction motions); *Nest Int'l, Inc. v. Balzamo*, 2012 U.S. Dist. LEXIS, *4 (D.N.J. May 3, 2012) (ordering discovery on preliminary injunction motion).

Here, the limited discovery requested by Hanmi is necessary for Hanmi fully to respond to and avoid undue prejudice from AstraZeneca's one-sided allegations of irreparable harm, and for the Court to properly address AstraZeneca's allegations. The expedited schedule requested by Hanmi is focused and provides Hanmi with the requisite documents and four separate depositions in less than 30 days, thus providing the parties and the Court (and potentially the Court of Appeals) with the full and complete record necessary to consider AstraZeneca's motion. However, recent communications with AstraZeneca counsel make clear that AstraZeneca will not even provide written responses to Hanmi's discovery requests until sometime tomorrow and that AstraZeneca plans to produce only a fraction of the documents requested, which are necessary for an understanding of the complete Nexium® market, now and in the future.

AstraZeneca takes the narrow and incorrect position that the only possible relevant topic to any alleged irreparable harm is the impact of Hanmi's imminent launch. (*See* Ex. B, Boland/Renk email communications.) However, facts pertaining to the entire Nexium® market and how it will play out in the future are critical to a proper assessment of AstraZeneca's claim of irreparable harm. Hanmi's requests seek standard market related information. The addition of new market players and timing thereof, including competitors of not just AstraZeneca, but also Hanmi, is crucial to properly assess any purported irreparable harm. AstraZeneca's plans to provide only a fractionated market picture and to shield highly pertinent information from Hanmi and the Court are improper. Critically, documents relating to the market impact of the generic and/or OTC launches in 2014 (*see* Ex. B) are necessary to demonstrate the impact of those other launches – not just Hanmi's – on AstraZeneca's business. In other words, without AstraZeneca's documents showing what the market will look like with other products launched in 2014, the Court will not be able to properly assess the impact of Hanmi's launch on AstraZeneca's business and, consequently, to properly assess the alleged irreparable harm to AstraZeneca. Accordingly, Hanmi respectfully requests that its proposed schedule be adopted, and the focused discovery set forth in Exhibit A be ordered.

While the merits of the pending Motion will be fully addressed on the schedule set by the Court, Hanmi notes that its impending mid-September launch presents no emergency or threat of "irreparable harm" – the hallmark of injunctive relief. AstraZeneca cannot meet the requirements for obtaining such relief here, whether in the form of a temporary restraining order or a preliminary injunction pending appeal.

Most fundamentally, in the Consent Judgment entered June 3, 2013 (D.I. 338), AstraZeneca conceded that the Hanmi Product does not infringe the two patents-in-suit under the Court's controlling claim constructions. In terms of likelihood of success on the merits, AstraZeneca's brief merely rehashes its prior claim construction arguments and should not cause the Court to seriously rethink its sound constructions, made on a full record, and affirmed on reconsideration. No new facts or change in law are presented by AstraZeneca to even remotely suggest a basis for success on the merits.

Likewise, even if *arguendo* AstraZeneca were successful on appeal in modifying the claim constructions, and Hanmi's esomeprazole strontium were later determined to infringe, AstraZeneca faces insurmountable hurdles in proving irreparable harm (as well as in proving that the balance of hardships and public interest favor injunctive relief). The extraordinary remedy of injunctive relief is unavailable when the purported harm may be redressed through an award of

money damages. *Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996); *see also Hybritech, Inc. v. Abbott Labs*, 849 F.2d 1446, 1457 (Fed. Cir. 1988) (injunctive relief preserves the legal interests of the parties against "future infringement which may have market effects never fully compensable in money"). As the district court noted in *Eli Lilly v. American Cyanamid*, predicted loss of market share and profits are easily compensable with money damages, and incidental "ripple effects" cannot convert reparable harm into irreparable harm. *Eli Lilly & Co. v. American Cyanamid Co.*, 896 F. Supp. 851, 860 (S.D. Ind. 1995). It is well-established that "neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial." *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991) (vacating preliminary injunction); *see also Novartis Corp. v. Teva Pharm. USA, Inc.*, 2007 U.S. Dist. LEXIS 42163, *90-91 (D.N.J. 2007) (possibility of lost sales, market share and price erosion "do not demand a preliminary injunction, especially where such losses, by all measure, appear to be calculable").

Beyond these stringent requirements for proving irreparable harm, here [redacted] For this and a multitude of additional reasons, no basis for an injunction pending appeal exists.

For these same reasons, any interim relief in the form of a temporary restraining order pending the completion of discovery and briefing on Hanmi's motion is inappropriate. AstraZeneca cannot show a likelihood of success on the merits and cannot show irreparable harm (or any of the other remaining requirements for injunctive relief). Moreover, AstraZeneca delayed nearly two weeks in filing this motion after Hanmi received final, public FDA approval of esomeprazole strontium on August 6, 2013. In addition, as [redacted] the risk of any irreparable harm to AstraZeneca is non-existent. This matter can be fully and fairly briefed and decided in accord with the discovery and schedule proposed by Hanmi, which requests entry of an order accordingly.

A proposed Order is submitted herewith. Hanmi counsel is available to be heard on this matter at the Court's earliest convenience (preferably other than Wednesday of this week).

Respectfully,

/s/ Mayra V. Tarantino

Mayra V. Tarantino

MVT:emp

cc: All Counsel of Record (via ECF & email)

EXHIBIT A

(Filed Under Seal)

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August 23, 2012

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Via Email

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Re: *AstraZeneca AB, et al. v. Hanmi USA, Inc., et al.*,
Civil Action No. 11-00760 (JAP)(TJB)

Dear Henry:

We write further to your recent email correspondence with Mark Boland regarding the schedule on AstraZeneca's Motion for Injunction Pending Appeal, filed Tuesday evening, August 20, 2013.

Your proposal yesterday that Hanmi file its opposition by August 30, 2013, with AstraZeneca filing its reply on September 5, 2013 and the Court holding a hearing the week of September 9, 2013 is neither realistic nor practical given the discovery necessary to provide the Court with a complete record. [redacted] is no surprise to AstraZeneca. And, as you and Mark discussed on August 8, 2013, the notice of final FDA approval of Hanmi's product was posted on the FDA website on August 7, 2013. It is eminently unfair to delay filing for two weeks after learning of final approval, and then insist that Hanmi respond on a truncated schedule, with no opportunity for discovery.

AstraZeneca's instant motion for an injunction pending appeal to stop the launch of Hanmi's product disregards both (i) the stipulated non-infringing status of that product as a result of the district court proceedings and (ii) [redacted] which will not necessarily be the case. Of particular pertinence with regard to the scheduling of the proceedings on AstraZeneca's instant motion, AstraZeneca relies on a 30-plus page memorandum of points and authorities and three lengthy substantive declarations presenting one-sided, unsupported assertions and a superficial view of the market and the purported harm to AstraZeneca.

Sughrue
SUGHRUE MION, PLLC

Under these circumstances, some narrowly-focused discovery on matters bearing on injunctive relief not addressed prior to the parties' settlement is necessary for Hanmi to respond to AstraZeneca's motion. *See, e.g.*, *Sawhorse Enterprises, Inc. v. Church & Dwight Co., Inc.*, No. 12-6811(FLW), 2013 U.S. Dist. LEXIS 48155, *11-12 (D.N.J. April 3, 2013) (discussing propriety of narrowly-tailored discovery on preliminary injunction motions); *Nest Int'l, Inc. v. Balzamo*, No. 12-2087 (JBS/KMW), 2012 U.S. Dist. LEXIS, *4 (D.N.J. May 3, 2012) (ordering discovery on preliminary injunction motion). In particular, Hanmi will need to take the depositions of AstraZeneca's three substantive declarants (per the enclosed notices) as well as a Rule 30(b)(6) deposition on the topics in the Rule 30(b)(6) notice accompanying this letter. Also attached is a set of document requests which, like the depositions of AstraZeneca's declarants and the Rule 30(b)(6) deposition, are narrowly focused on issues pertinent to proper resolution of AstraZenca's motion for injunctive relief.

Accordingly, we propose that AstraZeneca produce its documents in response to Hanmi's accompanying requests for production by next Friday, August 30, 2013. Hanmi then will review those documents, take the necessary depositions by September 20, 2013 and file its opposition papers by September 30, 2013. AstraZeneca can file any reply by October 7, 2013, and any hearing the Court may desire can be held thereafter.

Please advise today whether the foregoing proposed schedule meets with your approval. If you are in agreement, we can prepare an appropriate submission to the Court.

Very truly yours,

John B. Scherling

John B. Scherling

Enclosures
cc: Counsel of Record

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Attorneys for Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB Judge Joel A. Pisano Magistrate Judge Tonianne J. Bongiovanni

HANMI'S REQUESTS FOR THE PRODUCTION OF DOCUMENTS AND THINGS NOS. 1-7 REGARDING PLAINTIFFS' MOTION FOR INJUNCTION PENDING APPEAL

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Defendants and Counterclaim Plaintiffs, Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd, and Hanmi Holdings Co., Ltd.'s (collectively "Hanmi") hereby request that Plaintiffs and Counterclaim Defendants AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP KBI INC., and KBI-E INC. ("AZ" or "Plaintiffs") produce and/or permit Hanmi to inspect and copy each of the documents and things requested in Request Nos. 1-5 below on August 30, 2013.

DEFINITIONS

Notwithstanding any definition set forth below, each word, term, or phrase used in this Request is intended to have the broadest meaning permitted under the Federal Rules of Civil Procedure. Each definition below is intended to apply strictly for the purpose of these Requests, and has no bearing on Hanmi's positions with respect to claim construction or any other issue in the case. As used in these Requests, the below terms are to be interpreted in accordance with the following definitions:

1. The terms "Hanmi" or "Defendant" means Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd, and Hanmi Holdings Co., Ltd., the collective defendant group in this action.

2. The term "AZ," "Plaintiff" or "Plaintiffs," "you" and/or "your" means AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, KBI INC., and KBI-E INC., the collective group of plaintiffs in this action, and all predecessors, successors, subsidiaries, divisions, parents and/or affiliates thereof, past or present, and all past or present officers, directors, agents, employees, consultants, accountants, attorneys, representatives, and any other

person or entity acting on behalf of any of the foregoing.

3. The term "Person" or "Persons" means and includes any natural person, corporation, company, proprietorship, partnership, joint venture, association, firm, government entity or any other entity recognized in law, and shall include the owners, officers, directors, agents, trustees, parents, subsidiaries, affiliates, assignees, predecessors, and successors of each such "person."

4. The phrase "Third Party" means and includes any Person or Persons other than AZ and Hanmi.

5. The term "Communication(s)" means the transmittal of information by any means, and includes any transfer of information, ideas, opinions, or thoughts by any means, written, oral, or otherwise, at any time or place under any circumstances. The definition is not limited to transfers between persons but also includes other transfers, such as records and memoranda to file; any written letter, memorandum, e-mail or other document which was sent by one or more individuals to another or others; any telephone call between one or more individual and another or others, whether such call was by chance or prearranged, formal or informal; and any conversation or meeting between one or more individuals and another, whether such contact was by chance or prearranged, formal or informal.

6. "Document" and "Documents" shall have the broadest meaning ascribed to it by Rule 34(a) of the Federal Rules of Civil Procedure and mean any writing of any kind, including originals and all non-identical copies (whether different from the original by reason of any notation made on such copies or otherwise). The terms "Document" and "Document(s)" shall include, without limitation, the following items, whether printed or reproduced by any process, or written or produced by hand or stored in computer memory, magnetic or hard disk or other

data storage medium, and whether or not claimed to be privileged, confidential or otherwise excludable from discovery, namely, notes, letters, correspondence, Communications, e-mails, telegrams, memoranda, summaries or records of telephone conversations, summaries or records of personal conversations or meetings, diaries, reports, laboratory and research reports and notebooks, recorded experiments, charts, plans, drawings, diagrams, schematic diagrams, HDL, verilog, or other computer code, illustrations, product descriptions, product analyses, requests for proposals, documents related to proposed or actual product improvements or changes, users manuals or guides, installation guides or manuals, technical descriptions or specifications, product repair manuals or guides, photographs, video image, software flow charts or descriptions or specifications, product functional descriptions or specifications, minutes or records of meetings, summaries of interviews, reports, or investigations, opinions or reports of consultants, reports of patent searches, patent appraisals, opinions of counsel, agreements, reports or summaries of negotiations, brochures, pamphlets, advertisements, circulars, trade letters, press releases, drafts of documents, and all other material fixed in a tangible medium of whatever kind known to you or in your possession, custody, or control.

7. The term “concerning” means relating to, referring to, describing, evidencing, constituting, identifying, mentioning, discussing or analyzing.

8. The terms “Thing” and “Things” mean and include any tangible item other than a Document.

9. The term “Patents-in-suit” means the ’504 Patent and the ’192 Patent.

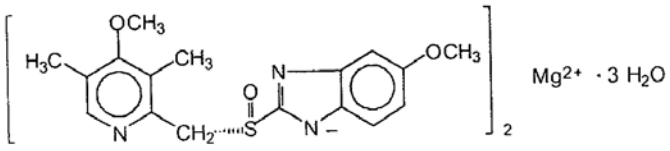
10. The term “Hanmi’s NDA” means the New Drug Application No. 202342 for which Hanmi is identified as applicant relating to proposed esomeprazole strontium products (20 mg, 40 mg).

11. The term "Hanmi Products" mean any of the pharmaceutical composition products containing esomeprazole strontium tetrahydrate that are the subject of Hanmi's NDA, and which have been approved by the FDA.

12. The term "AZ's NDA" means the New Drug Application No. 21153 for which AstraZeneca is identified as applicant, and which relates to esomeprazole magnesium trihydrate products (20 mg, 40 mg).

13. The term "Esomeprazole" means the (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in any form, including its salt forms, whether as a raw material active ingredient, formulated in any way, including into an administrable dosage form, or in any other form.

14. The term "Esomeprazole Magnesium Trihydrate" means the active compound present in Nexium® that is represented by the formula:



15. The term "Nexium®" means and includes the esomeprazole magnesium trihydrate formulation products sold by AstraZeneca LP under the name Nexium®, as described in paragraph 8 of the Complaint.

16. The present tense includes the past and future tenses. The singular includes the plural, and the plural includes the singular. "All" means "any and all," "any" means "any and all." "Including" means "including but not limited to." "And" and "or" encompass both "and" and "or." Words in the masculine, feminine or neutral form shall include each of the other genders.

INSTRUCTIONS

1. If, in responding to these Requests, AZ encounters any ambiguities when construing a request or definition, the response shall set forth the matter deemed ambiguous and the construction used in responding.

2. Whenever, in these Requests, AZ is asked to identify or produce a Document which is deemed by AZ to be properly withheld from production for inspection or copying:

A. If AZ is withholding a Document under claim of privilege (including, but not limited to, the work product doctrine), please provide the information set forth in Fed. R. Civ. P. 26(b)(5), including the type of Document, the general subject matter of the Document, the date of the Document, and such other information as is sufficient to identify the Document, including, where appropriate, the author, addressee, custodian, and any other recipient of the document, and where not apparent, the relationship of the author, addressee, custodian, and any other recipient to each other, in a manner that, without revealing the information claimed to be protected, will enable Hanmi to assess the applicability of the privilege or protection claimed by AZ;

B. If AZ is withholding the Document for any reason other than an objection that it is beyond the scope of discovery or that a request is unduly burdensome, identify as to each Document and, in addition to the information requested in ¶2.A, above, state the reason for withholding the Document.

3. When a Document contains both privileged and non-privileged material, the non-privileged material must be disclosed to the fullest extent possible without thereby disclosing the privileged material. If a privilege is asserted with regard to part of the material contained in a Document, the party claiming the privilege must clearly indicate the portions as to which the

privilege is claimed. When a Document has been redacted or altered in any fashion, identify as to each Document the reason for the redaction or alteration, the date of the redaction or alteration, and the person performing the redaction or alteration. Any redaction must be clearly visible on the redacted Document.

4. If production of any requested document(s) or thing(s) is objected to on the grounds that production is unduly burdensome, describe the burden or expense of the proposed discovery.

5. These Requests apply to all Documents and Things in the possession, custody or control of AZ, or otherwise known or available to AZ, regardless of their location and regardless of whether such Documents are held, known by or available to any of AZ's agents, employees, representatives, attorneys, or any other person.

6. If any Documents or Things requested were, but are no longer, in the possession, custody or control of AZ, or otherwise known or available to AZ, state what disposition was made of them and when.

7. If any Documents or Things requested have been lost or destroyed, describe in detail the circumstances of such loss or destruction and identify each lost or destroyed document (and all files that contained such documents).

8. Each Request seeks production of a Document or Thing in its entirety, without abbreviation or expurgation, including all attachments, or other matters affixed thereto.

9. All Documents and Things produced by AZ in response to these Requests shall include a production number.

10. Pursuant to Rule 34(b) of the Federal Rules of Civil Procedure, AZ is obligated to produce or make available for inspection all documents responsive to these Requests, as those

Documents are kept in the usual course of business or shall organize and label those Documents to correspond with these Requests.

11. In producing Documents, all Documents which are physically attached to each other in any of AZ's files shall be left so attached. Documents which are segregated or separated from other Documents whether by inclusion in binders, files, sub-files, or by use of dividers, tabs, or any other method, shall be left so segregated or separated. Documents shall be retained in the order in which they were maintained, in the file where found.

12. If the requested Documents are maintained in a file, the file folder shall be included in the response to these requests for production of those documents.

13. Pursuant to Rule 26(e)(2) of the Federal Rules of Civil Procedure, these Requests shall be deemed continuing so as to require further and supplemental responses and prompt supplemental production if AZ obtains or discovers additional information between the time of initial responses and the time of hearing or trial.

DOCUMENT REQUESTS

1. Documents sufficient to show AstraZeneca's lifecycle management strategies and future planning for Nexium® including, but not limited to: (a) financial projections that discuss the expected growth rate of sales for Nexium® (in dollars and units); (b) present and expected future promotional expenditures for Nexium®; (c) future line extension strategies for Nexium® including, but not limited to, introduction of an authorized generic version of Nexium® and/or an over-the-counter (OTC) version of Nexium®; and (d) expected reactions of AstraZeneca and third parties to competing products or generic versions of Nexium®.

2. Documents evidencing or reflecting expected effects of the introduction of Hanmi's Product, any other 505(b)(2) product, and/or any generic version of Nexium® on the U.S. sales or marketing of Nexium® including, but not limited to: (a) formulary placement of Nexium®; (b) "step edits" before Nexium® would be eligible for reimbursement; (c) any required prior authorization for approval to use Nexium®; (d) "Tier" placement of the Hanmi product, any other 505(b)(2) product, and/or any generic version of Nexium®; and/or (e) any impact the Hanmi's Product, any other 505(b)(2) product, and/or any generic version of Nexium® will have on the use of Nexium® within managed care plans.

3. All Documents that discuss the projected market share of AstraZeneca's esomeprazole magnesium product that will be achieved by, and projected lost unit sales, lost revenue, and lost profits relating to, (a) Hanmi's Product (either if introduced as a branded or a generic product), and (b) Ranbaxy and others' esomeprazole magnesium products entering in 2014.

4. Documents sufficient to show AstraZeneca's promotional, marketing and discounting/rebate/couponing strategies with respect to Nexium® in anticipation of or in reaction to potential generic entry by (a) Hanmi and (b) Ranbaxy and others in 2014, including any such discounting/rebate/couponing already underway with respect to Nexium®.

5. Documents, including data in electronic form, sufficient to show by month since the introduction of Nexium® in the U.S.: (a) the unit sales and gross revenues received by AstraZeneca and/or its affiliates from the sale of Nexium®; (b) corresponding net sales of Nexium®, including a summary itemization of each category of discount or rebate that is subtracted from gross sales to calculate net sales; (c) cost of goods sold including distribution costs; and (d) the resulting gross profits.

6. Documents sufficient to show all settlement agreements (including any amendments to these agreements) with other parties who have filed ANDAs for Nexium®, including but not limited to Ranbaxy, Teva, Dr. Reddy's, Sandoz and Lupin.

7. All Documents relating to potential "confusion" among doctors, patients, pharmacists, or managed care agents caused by the introduction of Hanmi's Product.

Date: August 23, 2013 By:

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Attorneys for Defendants and Counterclaim-Plaintiffs, Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

CERTIFICATE OF SERVICE

I hereby certify that on August 23, 2013, a copy of the foregoing Defendants' Requests for the Production of Documents and Things Nos. 1-7 to AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP KBI INC., and KBI-E INC. was served upon the following counsel via electronic mail:

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Attorneys for Defendants Hanmi USA, Inc.,
Hanmi Pharmaceutical Co., Ltd.,
Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC.,	:	
Plaintiffs and Counterclaim Defendants,	:	
v.	:	Civil Action No. 3:11-CV-00760-JAP-TJB
HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD.,	:	
Defendants and Counterclaim Plaintiffs.	:	

NOTICE FOR THE DEPOSITION OF ASTRAZENECA REGARDING PLAINTIFFS' MOTION FOR INJUNCTION PENDING APPEAL

Please take notice that pursuant to Federal Rule of Civil Procedure 26 and 30(b)(6) Defendants and Counterclaim Plaintiffs, Defendants and Counterclaim Plaintiffs, Hanmi USA, Inc., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd. (collectively "Hanmi") shall take the deposition of Plaintiff and Counterclaim Defendant, AstraZeneca AB ("AstraZeneca") before an officer authorized to administer oaths by oral examination of witnesses designated by Plaintiff to testify on its behalf with respect to the subjects set forth in the attached Schedule A commencing at 9:30 am on September 19, 2013 at the offices of Sughrue Mion, PLLC, 2100 Pennsylvania Avenue, N.W. in Washington D.C.

Plaintiff is requested to provide Hanmi's trial counsel, as soon as reasonably possible, a written designation of the name(s) and position(s) of the agent(s) or other persons who consent to testify on behalf of plaintiff, and, for each person so designated, the matters set forth in Schedule A to which the designee will testify.

The deposition will continue from day to day until completed, with such adjournments as may be necessary, and may be recorded by stenographic or videographic means.

DEFINITIONS

The Definitions set forth in Hanmi's Request for Production (Nos. 1-7) are hereby incorporated by reference, as if fully set forth herein. Notwithstanding any definition set forth therein, each word, term, or phrase used in these Topics is intended to have the broadest meaning permitted under the Federal Rules of Civil Procedure.

SCHEDULE A

1. The collection of documents in response to Hanmi's Requests for the Production of Documents and Things Nos. 1-7 Regarding Plaintiffs' Motion for Injunction Pending Appeal.

2. AstraZeneca's lifecycle management strategies and future planning for Nexium® including: (a) financial projections that discuss the expected growth rate of sales for Nexium® (in dollars and units); (b) present and expected future promotional expenditures for Nexium®; (c) future line extension strategies for Nexium® including, but not limited to, introduction of an authorized generic version of Nexium® and/or an over-the-counter (OTC) version of Nexium®; and (d) expected reactions of AstraZeneca and third parties to competing products or generic versions of Nexium®.

3. Expected effects, and the bases therefor, of the introduction of Hanmi's Product, any other 505(b)(2) product, and/or any generic version of Nexium® on the U.S. sales or marketing of Nexium® including: (a) formulary placement of Nexium®; (b) "step edits" before Nexium® would be eligible for reimbursement; (c) any required prior authorization for approval to use Nexium®; (d) "Tier" placement of the Hanmi product, any other 505(b)(2) product, and/or any generic version of Nexium®; and/or (e) any impact the Hanmi's Product, any other 505(b)(2) product, and/or any generic version of Nexium® will have on the use of Nexium® within managed care plans.

4. The projected market share of AstraZeneca's esomeprazole magnesium product that will be achieved by, and projected lost unit sales, lost revenue, and lost profits relating to, (a) Hanmi's Product (either if introduced as a branded or a generic product), and (b) Ranbaxy and others' esomeprazole magnesium products entering in 2014.

5. AstraZeneca's promotional, marketing and discounting/rebate/couponing strategies with respect to Nexium® in anticipation of or in reaction to potential generic entry by (a) Hanmi and (b) Ranbaxy and others in 2014, including any such discounting/rebate/couponing already underway with respect to Nexium®.

6. Since the introduction of Nexium® in the U.S., monthly (a) unit sales and gross revenues received by AstraZeneca and/or its affiliates from the sale of Nexium®, (b) corresponding net sales of Nexium®, including a summary itemization of each category of discount or rebate that is subtracted from gross sales to calculate net sales, (c) cost of goods sold including distribution costs, and (d) the resulting gross profits.

7. Settlement agreements (including any amendments to these agreements) with other parties who have filed ANDAs for Nexium®, including but not limited to Ranbaxy, Teva, Dr. Reddy's, Sandoz and Lupin.

8. Potential "confusion" among doctors, patients, pharmacists, or managed care agents caused by the introduction of Hanmi's Product.

9. Real world practice by managed care, physicians, pharmacists and patients with respect to prescription and substitution of non-AB rated 505(b)(2) products for branded pharmaceuticals.

Date: August 23, 2013 By:

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jscherling@sughrue.com

Attorneys for Defendants and Counterclaim-Plaintiffs, Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

CERTIFICATE OF SERVICE

I hereby certify that on August 23, 2013, a copy of the foregoing Notice for the Deposition of AstraZeneca Regarding Plaintiffs' Motion for Injunction Pending Appeal was served upon the following counsel via electronic mail:

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Bruce C. Haas, Esq.
Joshua Rothman, Esq.
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By: _____
Renita S. Rathinam, Esq.

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Attorneys for Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB Judge Joel A. Pisano Magistrate Judge Tonianne J. Bongiovanni

DEFENDANTS' NOTICE OF DEPOSITION OF ROBERT MARESCA

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 45, Defendants Hanmi USA, Inc., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd. (collectively "Hanmi") shall take the deposition upon oral examination under oath of Robert Maresca, beginning at 9:30 a.m., on the 16th day of September, 2013, and continuing from day to day until completed, in the offices of Sughrue Mion, PLLC, 2100 Pennsylvania Avenue, NW, Washington, DC 20037, or at such other time and place as may be agreed upon by counsel. The deposition will be recorded by videographic, stenographic, audio, audiovisual and/or real-time computer means, and is being taken for the purposes of discovery, for use at trial, and for such other purposes as permitted under the Federal Rules of Civil Procedure.

Date: August 23, 2013

By: 

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Attorneys for Defendants and Counterclaim-Plaintiffs, Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

CERTIFICATE OF SERVICE

I hereby certify that on August 23, 2013, a copy of the foregoing Defendants' Notice of Deposition of Robert Maresca was served upon the following counsel via electronic mail:

John E. Flaherty, Esq.
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Bruce C. Haas, Esq.
Joshua Rothman, Esq.
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Renita S. Rathinam, Esq.

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Attorneys for Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB Judge Joel A. Pisano Magistrate Judge Tonianne J. Bongiovanni

DEFENDANTS' NOTICE OF DEPOSITION OF ROBERT P. NAVARRO, PHARM. D.

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 45, Defendants Hanmi USA, Inc., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd. (collectively "Hanmi") shall take the deposition upon oral examination under oath of Robert P. Vavarro, Pharm. D., beginning at 9:30 a.m., on the 17th day of September, 2013, and continuing from day to day until completed, in the offices of Sughrue Mion, PLLC, 2100 Pennsylvania Avenue, NW, Washington, DC 20037, or at such other time and place as may be agreed upon by counsel. The deposition will be recorded by videographic, stenographic, audio, audiovisual and/or real-time computer means, and is being taken for the purposes of discovery, for use at trial, and for such other purposes as permitted under the Federal Rules of Civil Procedure.

Date: August 23, 2013

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Attorneys for Defendants and Counterclaim-Plaintiffs, Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

CERTIFICATE OF SERVICE

I hereby certify that on August 23, 2013, a copy of the foregoing Defendants' Notice of Deposition of Robert P. Vavarro, Pharm. D. was served upon the following counsel via electronic mail:

John E. Flaherty, Esq.
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Attorneys for Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB Judge Joel A. Pisano Magistrate Judge Tonianne J. Bongiovanni

DEFENDANTS' NOTICE OF DEPOSITION OF
NIMISH VAKIL, M.D. AGAF, FACG, FACGE

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 45, Defendants Hanmi USA, Inc., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd. (collectively "Hanmi") shall take the deposition upon oral examination under oath of Nimish Vakil, M.D. AGAF, FACG, FACGE, beginning at 9:30 a.m., on the 18th day of September, 2013, and continuing from day to day until completed, in the offices of Sughrue Mion, PLLC, 2100 Pennsylvania Avenue, NW, Washington, DC 20037, or at such other time and place as may be agreed upon by counsel. The deposition will be recorded by videographic, stenographic, audio, audiovisual and/or real-time computer means, and is being taken for the purposes of discovery, for use at trial, and for such other purposes as permitted under the Federal Rules of Civil Procedure.

Date: August 23, 2013

By:

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Attorneys for Defendants and Counterclaim-Plaintiffs, Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

CERTIFICATE OF SERVICE

I hereby certify that on August 23, 2013, a copy of the foregoing Defendants' Notice of Deposition of Nimish Vakil, M.D. AGAF, FACG, FACGE was served upon the following counsel via electronic mail:

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By: _____
Renita S. Rathinam, Esq.

EXHIBIT B

(Filed Under Seal)

From: Boland, Mark
To: hrenk@fchs.com
Cc: Scherling, John B.; bhaas@fchs.com; jrothman@fchs.com; pchen@fchs.com; mfurrow@fchs.com; jflaherty@mccarter.com; Patel, Ravin; estole@cov.com; jalexander@cov.com; Dzwonczyk, Michael R.; Rathinam, Renita S.; mtarantino@litedepalma.com; alite@litedepalma.com; Jacobs, Blair; Yoo, Ri; Rozos,Rick
Subject: RE: AZ v. Hanmi
Date: Monday, August 26, 2013 2:32:14 PM

Henry,

Thank you for your email. As we have discussed previously, we need all of the requested documents in advance of the noticed depositions. Whereas we propounded the document requests shortly after the filing of your motion last week, it appears (1) that you are refusing to produce many of the documents we requested, and (2) your delay in even giving us specific grounds of objection until tomorrow -- 5 days after receiving our requests -- leaves us no choice but to seek immediate relief from the Court regarding discovery and the schedule.

Your position that "to the extent [our] discovery requests go beyond the impact on AstraZeneca's Nexium business of Hanmi's threatened imminent launch (e.g., by seeking discovery on the impact on that business by generic launches in mid-2014), they plainly seek totally irrelevant information" is baseless. Facts pertaining to the entire Nexium® market and how it will play out in the future are critical to a proper assessment of AstraZeneca's claim of irreparable harm. You know very well that our requests seek standard market based information in this regard. In contrast to your narrow views, the addition of new market players and timing thereof, including competitors of not just AstraZeneca, but also Hanmi is crucial to properly assess any purported irreparable harm. Your plans to provide only a fractionated market picture and to shield highly pertinent information from us and the Court are improper. We are entitled to full discovery on the irreparable harm alleged by AstraZeneca, as well as each of the related assertions by your PI declarants.

As it appears that we are at an impasse regarding both the discovery and the schedule we have proposed, we will proceed with seeking the Court's assistance.

Mark

-----Original Message-----
From: Renk,Henry [mailto:HRenk@fchs.com]
Sent: Monday, August 26, 2013 10:55 AM
To: Boland, Mark
Cc: Scherling, John B.; bhaas@fchs.com; jrothman@fchs.com; pchen@fchs.com; mfurrow@fchs.com; jflaherty@mccarter.com; Patel, Ravin; estole@cov.com; jalexander@cov.com; Dzwonczyk, Michael R.; Rathinam, Renita S.; mtarantino@litedepalma.com; alite@litedepalma.com; Jacobs, Blair; Yoo, Ri; Rozos,Rick
Subject: RE: AZ v. Hanmi

Mark:

We hope to produce all relevant responsive documents by tomorrow, along with written responses to both Hanmi's document requests and its Rule 30(b)(6) deposition notice. As I specifically told you yesterday, to the extent your discovery requests go beyond the impact on AstraZeneca's Nexium business of Hanmi's threatened imminent launch (e.g., by seeking discovery on the impact on that business by generic launches in mid-2014), they plainly seek totally irrelevant information. In essence, this will be AstraZeneca's response to Hanmi's discovery requests. Your unsupported assertion of relevance is misplaced.

Under the circumstances, [redacted] we again ask Hanmi to begin its depositions on the dates we offered yesterday. If you refuse, or continue to insist on a schedule which delays resolution of the injunction motion, we will seek a conference with Judge Pisano on Wednesday.

Henry

Henry J. Renk
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-----Original Message-----
From: Boland, Mark [mailto:mboland@sughrue.com]
Sent: Sunday, August 25, 2013 9:16 PM
To: Renk,Henry; Renk,Henry
Cc: Scherling, John B.; Haas, Bruce; Rothman,Joshua; Chen, Patrick L.; Furrow, Michael; jflaherty@mccarter.com; Patel, Ravin; estole@cov.com; jalexander@cov.com; Dzwonczyk, Michael R.; Rathinam, Renita S.; mtarantino@litedepalma.com; alite@litedepalma.com; Jacobs, Blair; Yoo, Ri
Subject: RE: AZ v. Hanmi

Henry, Thanks, but:

1) Without a commitment that the complete set of documents we requested will be produced by a date certain -- all of which are relevant and a production date you fail to provide -- and giving us an opportunity to review and process, your proposed deposition dates fall precisely into the prejudice arena we previously advised.

2) If you actually have specific objections to any discovery requests we made (within 48 hours of receiving your papers and lengthy declarations), please advise so that the parties can address the areas that can't be resolved without going to the Court. Your vague emails are not sufficient. We're prepared to go before the Court this week as to any specific objections to our document requests and 30(b)(6) categories, but obviously such issues should be addressed before depositions to avoid recall and delay.

3) All of this shows that the deposition dates you are proposing -- especially this coming week -- are not fair or workable and thus highly prejudicial. However, with significant movement on your part to get us all the relevant documents without objection we will be in a position to move forward quickly, as per our prior correspondence.

Mark

-----Original Message-----
From: Renk,Henry [mailto:HRenk@fchs.com]
Sent: Sunday, August 25, 2013 8:00 PM
To: hrenk@fchs.com
Cc: Boland, Mark; Scherling, John B.; bhaas@fchs.com; jrothman@fchs.com; pchen@fchs.com; mfurrow@fchs.com; jflaherty@mccarter.com; Patel, Ravin; estole@cov.com; jalexander@cov.com; Dzwonczyk, Michael R.; Rathinam, Renita S.; mtarantino@litedepalma.com; alite@litedepalma.com; Jacobs, Blair; Yoo, Ri
Subject: Re: AZ v. Hanmi

Mark: Dr. Vakil could be available for deposition as early as the afternoon of August 30 in Milwaukee, or in Washington, DC on Saturday, August 31, or in Milwaukee on September 3, morning. Dr. Navarro's deposition could be on September 3 or 4. We will advise tomorrow about Mr. Maresca.

Sent from my iPad

On Aug 25, 2013, at 5:33 PM, "Renk,Henry" <HRenk@fchs.com> wrote:

> Mark: as I told you on Friday, we will endeavor to complete document production as early as possible

this week. We note that your document requests seek totally irrelevant documents, such as AstraZeneca's plans to respond to a generic launch next May-June. The only possible relevant topic is the impact of Hanmi's imminent launch. We are collecting such documents.
>
> moreover, you will need to start your depositions, and file your opposition, much sooner than your proposed schedule allows. Since Hanmi apparently refuses to even [redacted]
>
> We'll talk further tomorrow.
>
> Henry
>
> Sent from my iPad
>
> On Aug 25, 2013, at 5:10 PM, "Boland, Mark" <mboland@sughrue.com> wrote:
>
>> Henry:
>>
>> Further to our discussion on Friday afternoon, we have yet to hear
>> back from you regarding a specific response to our proposed PI
>> schedule. We did take another look at our proposal, and if you can
>> advance the document production completion date to sooner than Aug.
>> 30th, we would be reasonable in attempting to move up certain other
>> dates. However, we will need time to review the documents, discuss
>> with experts as appropriate and prepare for depositions, which our
>> schedule provides. If your proposal would not permit us to fairly
>> complete the discovery needed to respond, it would obviously be
>> highly prejudicial.
>>
>> In any case, if we do not have an agreed schedule by Monday mid-day
>> (and if we don't receive something from you soon we won't have an
>> ability to discuss it with Hanmi), we'll plan to arrange an
>> immediate call with Judge Pisano.
>>
>> Mark
>> -----Original Message-----
>> From: Scherling, John B.
>> Sent: Friday, August 23, 2013 4:07 PM
>> To: hrenk@fchs.com
>> Cc: bhaas@fchs.com; jrothman@fchs.com; pchen@fchs.com;
>> mfurrow@fchs.com; jflaherty@mccarter.com; Patel, Ravin;
>> estole@cov.com; jalexander@cov.com; Boland, Mark; Dzwonczyk, Michael
>> R.; Rathinam, Renita S.; mtarantino@litedepalma.com;
>> alite@litedepalma.com; Jacobs, Blair; Yoo, Ri
>> Subject: RE: AZ v. Hanmi
>>
>> Henry- [redacted] as Mark has
>> previously advised. We will be in touch with you shortly to meet
>> and confer, and then to set up a call with Judge Pisano for early
>> next week assuming we will not reach agreement. John
>>
>> -----Original Message-----
>> From: Renk,Henry [mailto:HRenk@fchs.com]
>> Sent: Friday, August 23, 2013 11:57 AM
>> To: Yoo, Ri
>> Cc: bhaas@fchs.com; jrothman@fchs.com; pchen@fchs.com;
>> mfurrow@fchs.com; jflaherty@mccarter.com; Patel, Ravin;
>> estole@cov.com; jalexander@cov.com; Boland, Mark; Dzwonczyk, Michael

>> R.; Rathinam, Renita S.; Scherling, John B.;
>> mtarantino@litedepalma.com; alite@litedepalma.com; Jacobs, Blair
>> Subject: Re: AZ v. Hanmi
>>
>> John: I have not had an opportunity to discuss your letter with all concerned, but my own reaction is that your proposed schedule is impossible unless Hanmi will agree to postpone its launch until the Court decides the matter. Will Hanmi so agree? let me know immediately.
>>
>> Henry
>>
>> Sent from my iPad
>>
>> On Aug 23, 2013, at 1:57 PM, "Yoo, Ri" <ryoo@sughrue.com> wrote:
>>
>>> Dear Counsel:
>>>
>>> Please see attached.
>>>
>>> Regards,
>>> Ri
>>> <2013-08-23 Scherling to Renk.pdf>
>>> <Hanmi Requests for the Production of Documents and Things Nos. 1-7
>>> Re Motion for Injunction.pdf> <Notice for the Deposition of
>>> AstraZeneca Re Motion for Injunction Pending Appeal.pdf> <Notice of
>>> Deposition of Robert Maresca.pdf> <Notice of Deposition of Robert
>>> Navarro.pdf> <Notice of Deposition of Nimish Vakil.pdf>
>> ----------
>> ------ This email message and any attachments are intended for the
>> use of the addressee(s) indicated above. Information that is privileged or otherwise confidential may be contained therein. If you are not the intended recipient(s), you are hereby notified that any dissemination, review or use of this message, documents or information contained therein is strictly prohibited. If you have received this message in error, please immediately delete it and notify us by telephone at (212) 218-2100. Thank you.
>>
>>

EXHIBIT C

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